Proposed Decision Memo for Cardiac Catheterization Performed In Other Than A Hospital Setting (CAG-00166N)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes to repeal the National Coverage Determination (NCD) Manual §20.25.

Back to Top

Proposed Decision Memo

TO: Administrative File CAG: # 00166N Cardiac Catheterization Performed In Other Than A Hospital

Setting

FROM:

Steve E. Phurrough, MD, MPA

Director, Coverage and Analysis Group (CAG)

Marcel E. Salive, MD, MPH Director, Division of Medical and Surgical Services

JoAnna F. Baldwin Policy Analyst, CAG

Joseph Chin, MD Medical Officer, CAG

SUBJECT: Coverage Decision Memorandum for Cardiac Catheterization Performed In Other Than a Hospital

Setting

DATE: October 21, 2005

I. Decision

The Centers for Medicare and Medicaid Services (CMS) proposes to repeal the National Coverage Determination (NCD) Manual §20.25.

II. Background and History of Medicare Coverage

The Medicare National Coverage Policy for Cardiac Catheterization Performed In Other

Than A Hospital Setting was implemented August 1, 1979 in the NCD Manual §20.25:

Cardiac catheterization performed in a hospital setting for either inpatients or outpatients is a covered service. The procedure may also be covered when performed in a freestanding clinic when the carrier, in consultation with the appropriate Peer Review Organization (PRO), determines that the procedure can be performed safely in all respects in the particular facility. Prior to approving Medicare payment for cardiac catheterizations performed in freestanding clinics, carriers must request PRO review of the clinic. 1

At that time, the carriers (Medicare Part B contractors) were responsible for consulting with the PROs (subsequently renamed Quality Improvement Organizations [QIOs]) prior to approving Medicare payment. In 1979, the PROs were conducting reviews as part of their scope of work. In the early 1990's, the approach and functions of the PROs changed from case reviews to quality improvement. The PROs stopped their review of freestanding cardiac catheterization facilities when it was no longer included in the PRO scope of work in 1995. The language in the NCD Manual was never revised to reflect the change in QIO functions. Therefore, the policy that remains in the NCD Manual contains outdated language that implies QIO activity outside their scope of work.

III. Timeline

8/1/79 CMS implemented the national policy for cardiac catheterization in other than a hospital setting requiring PRO involvement.

Printed on 4/13/2012. Page 2 of 10

1995	Review of cardiac catheterization facilities was no longer included in the PRO scope of work.
10/8/02	CMS opened the NCD and requested public comment.
1/16/03	CMS extended the due date of the NCD.
2/10/03	CMS extended the due date of the NCD.

IV. Evidence

PubMed was searched from 1999 using the term "cardiac catheterization laboratory". Within this time period, no controlled trials were identified comparing patient outcomes and safety of cardiac catheterizations performed in freestanding facilities with hospital-based procedures. The search did identify, however, a consensus document from the American College of Cardiology (ACC) and The Society for Cardiac Angiography and Interventions (SCA&I) and an article discussing trends in the growing number of freestanding facilities in the United States².

Guidelines, consensus panels and expert opinion

The ACC/SCA&I Clinical Expert Consensus Document: Cardiac Catheterization Laboratory Standards discusses recommended requirements for performing cardiac catheterizations in freestanding facilities. The freestanding facility should have a formal relationship with a tertiary hospital for the emergency transfer of patients, have equipment for intubation and ventilatory support, and have quality assurance and quality improvement programs in place. In addition, the physicians must be able to perform endotracheal intubations and insert an intra-aortic balloon pump. Patient selection is critically important in freestanding facilities without surgical backup, and is specifically addressed in the document. The consensus document recommends that only diagnostic cardiac catheterizations be performed in freestanding facilities and lists patient inclusion and exclusion criteria; no therapeutic procedures are recommended.

The ACC and SCA&I document stresses the importance of quality assurance outlining clinical proficiency, complication rate, diagnostic accuracy and patient outcomes as critical aspects of a cardiac catheterization lab. The document reports that the major complication rate for diagnostic cardiac catheterizations is estimated between 1% and 2%, which the experts feel is acceptably low3.	
External Technology Assessment	

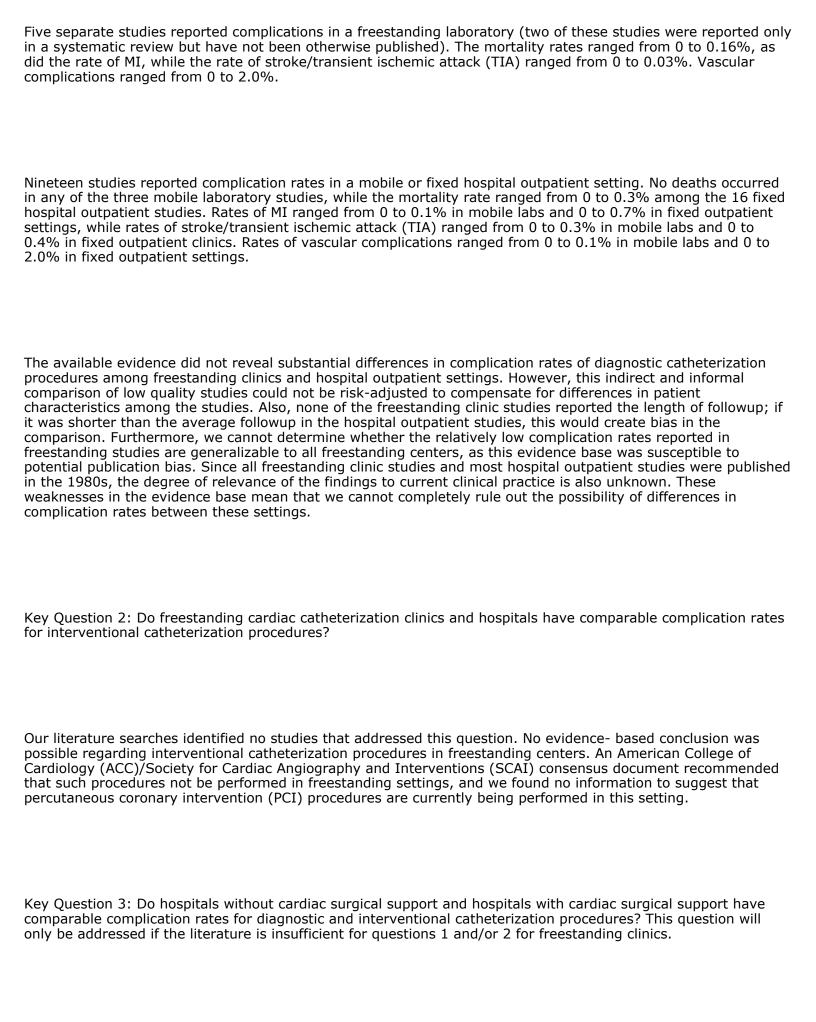
In 2005, the Agency for Healthcare Research and Quality commissioned a technology assessment on cardiac catheterization in freestanding clinics to answer 5 key questions:

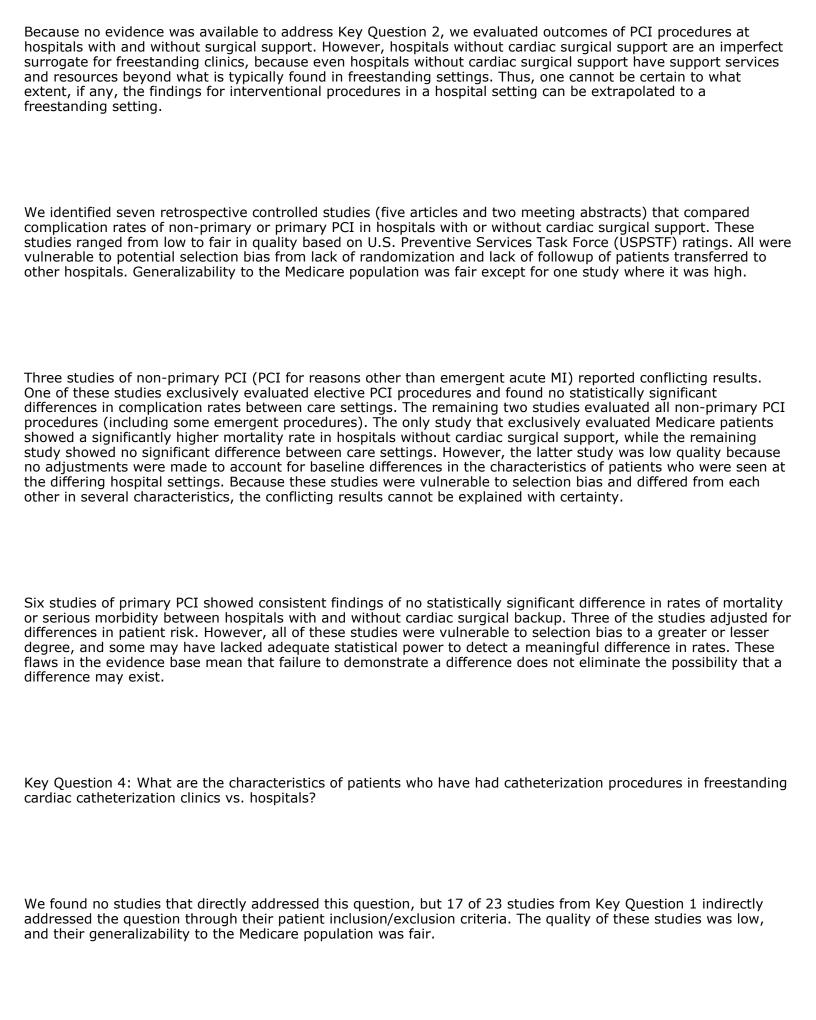
- 1. Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for diagnostic catheterization procedures?
- 2. Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for interventional catheterization procedures?
- 3. Do hospitals without cardiac surgical support and hospitals with cardiac surgical support have comparable complication rates for diagnostic and interventional catheterization procedures?
- 4. What are the characteristics of patients who have had catheterization procedures in freestanding cardiac catheterization clinics vs. hospitals?
- 5. What are the current state regulations, Certificate of Need (CON) requirements, and oversight procedures for freestanding cardiac catheterization clinics?

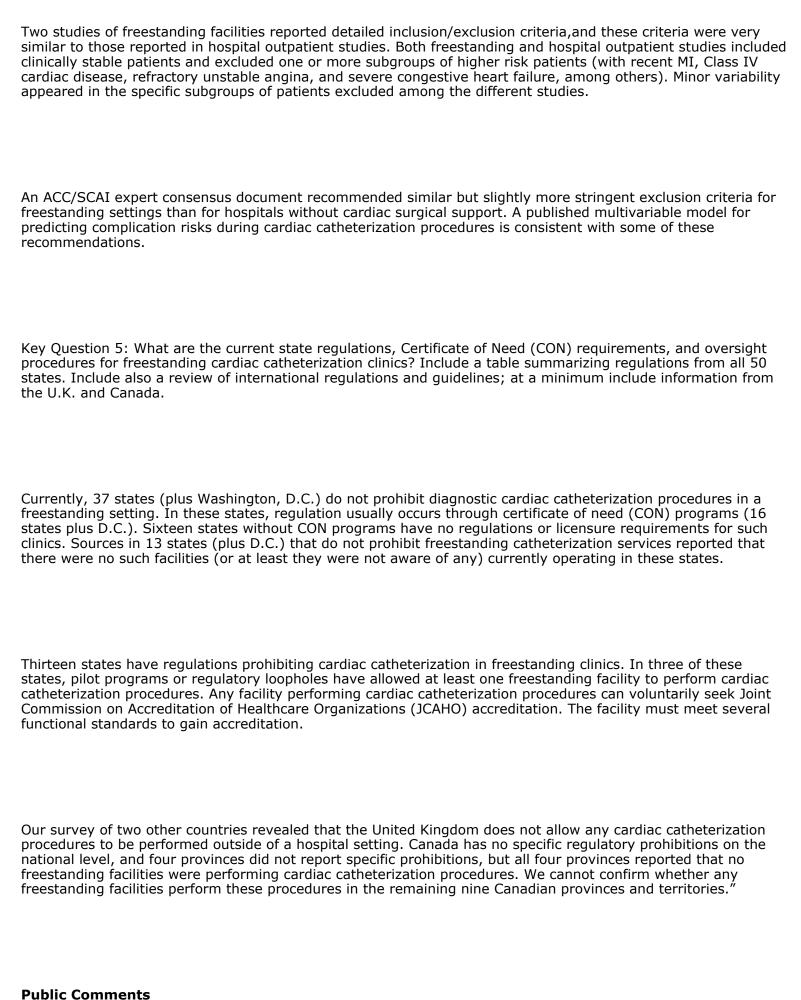
The assessment was performed by ECRI and stated (reproduced exactly from the report⁴):

"Key Question 1: Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for diagnostic catheterization procedures?

After searching the literature, retrieving articles, and applying the inclusion/exclusion criteria, we identified 23 publications that reported complication rates of diagnostic catheterization procedures in a freestanding or hospital outpatient setting. None of these studies directly compared complication rates in freestanding and hospital settings. Thus, the quality of the evidence is low. The studies' generalizability to the Medicare population was fair.







i abiic commicites

CMS received comments in support of this change jointly from the ACC and SCA&I. The ACC and SCA&I acknowledge that due to changes in their scope of work, PROs have not provided oversight of freestanding facilities and that procedures have continued to be performed safely. They included in the comments a copy of the ACC/SCA&I Clinical Expert Consensus Document: Cardiac Catheterization Laboratory Standards. 5

The American Hospital Association (AHA) submitted comments expressing concern over the lack of quality controls in outpatient facilities and suggesting that freestanding cardiac catheterization facilities be subject to quality standards and monitoring/enforcement requirements that are comparable to those applied to hospital outpatient departments for similar procedures. AHA also states that there is an inherently greater risk in performing the procedure in an outpatient setting where there are no emergency or cardiac surgery services on site.

V. CMS Analysis

National coverage determinations (NCDs) are determinations made by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act \S 1862(I)(6)(A). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." \S 1862(a)(1)(A).

The original coverage policy for cardiac catheterization performed in freestanding centers in 1979 was developed at a time when the PROs (now known as QIOs) were conducting facility reviews as part of their scope of work. In the early 1990's, the approach and functions of the PROs changed from case reviews to quality improvement. In 1995, the review of freestanding cardiac catheterization was removed from the PRO scope of work, effectively ending PRO review of these clinics. The language in the NCD Manual was not yet revised to reflect the change in current QIO functions. Thus CMS initiated this decision to update the NCD Manual based on current evidence and practice.

When considering the evidence, specifically the AHRQ technology assessment, nearly half of the states either prohibit diagnostic cardiac catheterization in freestanding settings or have regulations or licensing programs that have prevented programs from being established. The technology assessment found that 13 states have regulations specifically prohibiting cardiac catheterization in freestanding clinics, although three of these states do have such facilities. Further, it appears that ongoing review and monitoring of cardiac catheterizations performed in freestanding clinics continues in many states. The regulation and review of the freestanding clinics that do these procedures has correctly resided with the states. If a need arises for review, QIOs can still assist with this activity as part of their discretionary local functions. CMS concludes that the NCD Manual should not reflect inaccurate QIO functions.

As noted in the technology assessment, there is suggestive but insufficient evidence to determine if net health outcomes of cardiac catheterizations performed in freestanding clinics is comparable to for cardiac catheterizations performed in the hospital setting. Comparative evidence on coronary catheter-based interventions was insufficient as well. Until a more complete evaluation of the safety and effectiveness of cardiac catheterizations performed in freestanding clinics is conducted, it appears prudent to consider the risks and benefits on a state by state basis. Therefore, we conclude that cardiac catheterization may be covered when performed in a freestanding clinic at carrier discretion. Local carrier discretion prevails in the event CMS does not have national policy on a particular service. Therefore, rather than propose national policy that explicitly states contractor discretion regarding coverage this service, CMS proposes that the existing national policy on cardiac catheterization in freestanding clinics be repealed.

VI. Conclusion

The Centers for Medicare and Medicaid Services (CMS) proposes to repeal the National Coverage Determination (NCD) Manual §20.25.

- 1 NCD Manual §20.25
- ² Sheldon, WC et al. 2001
- 3 Bashore, TM et al. 2001

